PSJ3 Exhibit 466

Food Marketing Institute

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901 North Glebe Road Arlington, VA 22203 703-787-0000 www.healthcaredistribution.org

National Association of Chain Drug Stores

413 North Lee Street Alexandria, VA 22314 703-549-3001 www.nacds.org **National Community Pharmacists Association**

100 Daingerfield Road Alexandria, VA 22314 703-683-8200 www.ncpanet.org

September 6, 2011

Mr. Joseph T. Rannazzisi
Deputy Administrator
Office of Diversion Control
Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Rannazzisi:

RE: Controlled Substances and List I Chemical Registration and Re-registration Application Fees [Docket No. DEA-346P] RIN 1117-AB32

The Food Marketing Institute (FMI), Healthcare Distribution Management Association (HDMA), National Association of Chain Drug Stores (NACDS), and National Community Pharmacists Association (NCPA) are pleased to provide joint comments regarding DEA's proposed rule: Controlled Substances and List I Chemical Registration and Re-registration Application Fees.

FMI conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores and 15,000 pharmacies. Their combined annual sales volume of \$680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

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HDMA is the national association representing primary healthcare distributors, the vital link in the healthcare system. Each business day, HDMA member companies ensure that more than nine million prescription medicines and healthcare products are delivered safely and efficiently to 164,000 pharmacies, hospitals, nursing homes, clinics and others nationwide. HDMA and its members work daily to provide value and contain costs, saving the nation's healthcare system an estimated \$32 billion per year. For more information, visit www.HealthcareDistribution.org.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate 39,000 pharmacies, and employ more than 2.7 million employees, including 118,000 full-time pharmacists. They fill nearly 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their \$830 billion in annual sales. Every \$1 spent in these stores creates a ripple effect of \$1.96 in other industries, for a total economic impact of \$1.57 trillion, equal to 11 percent of GDP. NACDS represents 137 chains that operate these pharmacies in neighborhoods across America, and NACDS members also include more than 900 pharmacy and consumer packaged goods suppliers and service providers, and over 60 international members from 23 countries. For more information about NACDS, visit www.NACDS.org.

NCPA® represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a \$93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. To learn more go to www.ncpanet.org or read NCPA's blog, The Dose, at http://ncpanet.wordpress.com

We understand from DEA's analysis for the proposed rule you considered four options for fee calculation methodologies and decided to maintain the existing weighted-ratio methodology. Based on the proposal, if implemented, this methodology would require DEA to increase registration fees for all registrant groups.

Similar to comments raised by regulated groups in 2006 when DEA last proposed a fee increase, we ask DEA to renew your efforts at cost savings before proposing a fee increase on registrants. In these challenging economic times, we are all struggling to become more efficient and reduce waste, including federal and state governments. Prior to implementing any fee increase, we urge DEA to raise the priority of the cost savings and efficiency initiatives that DEA has undertaken. Accordingly, we urge the DEA to continue its ongoing efforts to improve efficiencies and identify additional cost saving measures.

Additionally, while we appreciate that DEA allows a waiver from the List I chemical registration requirements if such person is already registered with DEA to distribute controlled substances, the waiver does not apply to all listed chemicals. We recommend extending the waiver to all listed chemicals distributed by controlled substances registrants to help increase efficiency by eliminating the burden of maintaining two different registration numbers and paying two separate fees. Extending the waiver will not compromise security since those storing controlled substances are known to DEA through their controlled

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substance registration, and generally have more stringent security measures than those registered solely as listed chemical handlers.

We do understand that DEA continues to battle the ongoing problem of prescription drug abuse, as do we. We appreciate that DEA provided in the NPRM's preamble an explanation of the functions for which DEA plans to use the additional registration fees, as well as a general description of the agency's financial oversight. However, we urge more clarity about how DEA plans to use the additional registration funding to curb the problem of prescription drug abuse should the proposed rule become final. We believe that addressing the problem of prescription drug abuse should be among DEA's highest priorities and we would welcome more information or dialogue about how additional resources would be deployed in this manner.

Finally, we would like to take this opportunity to reiterate our general concern about the notion that registrants are responsible for controlled substance diversion because they hold, store, and distribute large quantities of these products for legitimate purposes. The major sources of controlled substance abuse and diversion are illicit entities that operate via the Internet and through highly suspect entities informally called "pill mills." Although we understand that DEA is mandated to collect registration fees from legitimate entities, we urge DEA to use this funding to pursue the illegitimate actors.

Respectfully submitted,

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